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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/695,795	10/23/2000	Jeffrey D. Rothstein	JHU1650-2	3376

7590

03/05/2002

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EXAMINER

WEGERT, SANDRA L

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 03/05/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/695,795

Applicant(s)

ROTHSTEIN ET AL.

Examiner

Sandra Wegert

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-88 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10 and 78-82, drawn to Glutamate Transporter Associated Proteins, classified in class 530, subclass 300+. Furthermore, applicant is required to elect one SEQ ID NO corresponding to a GTRAP.
- II. Claims 11-13, 18-22, 83 and 84, drawn to polynucleotides encoding Glutamate Transporter Associated Proteins and methods of making GTRAPs recombinantly, classified in class 435, subclass 69.1. Applicant is required to elect one SEQ ID NO corresponding to a GTRAP.
- III. Claims 14-17 and 85-88, drawn to antibodies against GTRAP, classified in class 530, subclass 387.1. Applicant is required to elect one SEQ ID NO corresponding to a GTRAP.
- IV. Claim 23, drawn to a polypeptide ligand that interacts with a short peptide segment, classified in class 530, subclass 3+. Furthermore, applicant is required to elect one SEQ ID NO corresponding to an epitope or binding site.
- V. Claim 24, drawn to a polynucleotide encoding a polypeptide ligand, classified in class 530, subclass 3+. Furthermore, applicant is required to elect one SEQ ID NO corresponding to a polynucleotide encoding an epitope or binding site.
- VI. Claim 25, drawn to an artificial polypeptide "bait" sequence, classified in class 530, subclass 300+.

VII. Claim 26, drawn to an artificial polypeptide "bait" sequence, classified in class 530, subclass 300+.

VIII. Claims 27-29 and 34-44, drawn to a method of identifying compounds that modulate a change in glutamate transport, classified in class 435, subclass 35+.

IX. Claims 27, 30, 31 and 34-44, drawn to a method of identifying compounds that modulate cytoskeletal stability, classified in class 435, subclass 35+.

X. Claims 27, 32, 33 and 34-44, drawn to a method of identifying compounds that modulate a cellular response mediated by a GTRAP, classified in class 435, subclass 35+.

XI. Claims 45-61, drawn to a method of treating a disorder associated with glutamate transport. Classification dependent upon structure of recited compound.

XII. Claims 62 and 63, drawn to a transgenic animal, classified in class 800, subclass 8+.

XIII. Claims 64-69, drawn to an animal "knockout", classified in class 800, subclass 8+.

XIV. Claims 70-77, drawn to computer hardware and software for nucleic acid sequence comparison, classified in class 702, subclass 20+.

Furthermore, restriction to one of the following inventions is required under 35 U.S.C. 121:

A) Chose a SEQ ID NO: corresponding to a GTRAP:

- i) SEQ ID NO: 1,
- ii) SEQ ID NO: 2,
- iii) SEQ ID NO: 3,

- iv) SEQ ID NO: 4,
- v) SEQ ID NO: 5,
- vi) SEQ ID NO: 6,
- vii) SEQ ID NO: 7 or,
- viii) SEQ ID NO: 8.

Corresponding to Groups 23 and 24, restriction to one of the following inventions is required under 35 U.S.C. 121:

B) Chose a SEQ ID NO: corresponding to an epitope or binding site:

- i) SEQ ID NO: 9, or
- ii) SEQ ID NO: 10.

The inventions are distinct, each from each other because of the following reasons:

Inventive Groups I and II are related as process of making and product made. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product, or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05 (f)). In the instant case the polypeptide can be prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols.

Inventions I and III are independent and distinct, each from the other, because they are products which presumably possess characteristic differences in structure and function and each

has an independent utility that is distinct for each invention which cannot be exchanged. In the instant case the antibody of Group III can be used for immunoprecipitation of the protein of interest or used therapeutically.

Inventions I and IV are independent and distinct, each from the other, because they are products which presumably possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. In the instant case the ligand of Group IV can be used to visualize a GTRAP.

Inventions I and V are independent and distinct, each from the other, because they are products which presumably possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. In the instant case the ligand of Group IV can be used to visualize a GTRAP.

Invention I is independent and distinct from Inventions VI and VII, because they are products which presumably possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. In the instant case the "bait" polypeptides of Groups VI and VII can be used to isolate a GTRAP.

Invention I is independent and distinct from Inventions XII and XIII, because they are products which presumably possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. The polypeptide of Invention I can be used to generate antibodies, while the transgene animals of Inventions XII and XIII can be used to study the physiological function of the GTRAP.

Inventions II and III are independent and distinct, each from the other, because they are products which presumably possess characteristic differences in structure and function and each

has an independent utility that is distinct for each invention which cannot be exchanged. The polynucleotides are used to recombinantly produce a GTRAP polypeptide. The antibody of Group III can be used for immunoprecipitation of the protein of interest or used therapeutically.

Inventions II is independent and distinct from Inventions IV, VI and VII because they are products which presumably possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. The polynucleotides are used to recombinantly produce a GTRAP polypeptide. The polypeptides can be used for immunohistochemical localization of the protein of interest or used therapeutically.

Invention II is unrelated to Invention V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acids of Groups II and V produce different polypeptides.

The methods of Inventions II, VIII-XI and XIV are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

Inventions II, XII and XIII are independent and distinct, each from the other, because they are products which presumably possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. The transgene animals of Inventions XII and XIII can be used to study the physiological function of the transporter peptide. Inventions XII, XIII and XIV may also be related to Invention II as product and process of use. The inventions can be shown to be distinct

if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the polynucleotide of Group II can be used for gene therapy or to produce the protein of Invention I.

Invention III is unrelated to Inventions IV-XIV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody of Group III is neither used with the products nor produced by any of the methods or products of Groups III-XIV. Inventions VIII, IX and X may be related to Invention III as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the antibody of Group III can be used to immunoprecipitate a GTRAP protein.

Inventive Groups IV and V are related as process of making and product made. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product, or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05 (f)). In the instant case the polypeptide can be prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols.

Invention IV is unrelated to Inventions VI and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the ligand of Group IV is used for a different purpose than the polypeptides of Groups VI and VII. Similarly, Inventions VI and VII are used separately to isolate different targets.

Invention IV is related to inventions VIII-XI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the polypeptide of Group IV can be used for immunolocalization of the protein of interest.

Invention IV is unrelated to Inventions XII-XIV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the ligand of Group IV is neither used with the products nor produced by the methods of Inventions XII-XIV.

Invention V is unrelated to Inventions I-III and VI-XIV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotide encoding the ligand is neither used with the products nor produced by the methods of Inventions I-III and VI-XIV.

Invention VI is unrelated to Invention VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the polypeptides of Groups VI and VII are used separately to isolate different targets.

Invention VIII is unrelated to Inventions XII and XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the method of searching for ligands does not use or produce the transgenic animals of Groups XII and XIII.

Invention IX is unrelated to Inventions XII and XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the method of searching for compounds that modulate cytoskeletal stability does not use or produce the transgenic animals of Groups XII and XIII.

Invention X is unrelated to Inventions XII and XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the method of searching for compounds that modulate GTRAP does not use or produce the transgenic animals of Groups XII and XIII.

Invention XI is unrelated to Inventions XII and XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of

operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the method of treating a GTRAP related disorder does not use or produce the transgenic animals of Groups XII and XIII.

Invention XII is unrelated to Invention XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the knockout animal and the animal containing the transgene are not used together.

Invention XIV is unrelated to Inventions XII and XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the method of using computer algorithms to search for nucleic acid sequences does not use or produce the transgenic animals of Groups XII and XIII.

Furthermore, each polypeptide or nucleic acid sequence in restrictions (A) – (B) represents a patentably distinct invention. The sequences are independent and distinct, each from the other, because they have different putative functions, different structures, and require completely different search terms, starting points and strategies.

Because these inventions are distinct for the reasons given above and the search required for each group is unique, and because each protein or nucleic acid in restrictions (A)-(B) requires

a completely separate search, as well as by their different classifications, divergent subject matter and different search requirements, restriction for examination purposes as indicated is proper.

In response to this requirement, applicants must elect from Inventive Groups I through XIV, and must additionally elect from Groups (A) - (B). Applicant is advised that in order for the reply to this requirement to be complete it must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 8:30 AM to 5:00 PM (Eastern Time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW
2/20/02

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER